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(54) A balloon device for implanting an aortic intraluminal prosthesis for repairing aneurysms

Ballongerät zum Einpflanzen einer aortischen, intraluminalen Prothese

Dispositif à ballonet pour implanter une prothèse aortique intraluminale destinée à la réparation des aneurisms

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(56) References cited:
EP-A- 277 369
EP-A- 277 370
WO-A-90/01969
WO-A-90/15582
DE-A- 3 205 942
US-A- 4 562 596
US-A- 4 577 631

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Description

The present invention relates to a balloon device for implanting an aortic or aortobiiliac intraluminal prosthesis for repairing aneurysms, more precisely an arrangement of inflatable balloons which are arranged upon a catheter in order to adapt the means of attachment of a tubular prosthesis to the walls of the aorta.

Intravascular devices, called "stents," which are placed in the organism by means of introducers on balloon catheters, are known.

These stents, used as a means of attachment for intravascular prostheses, are deformed by increasing their diameter when subjected to expansion from inside by inflation of a balloon, until they are imprisoned against the internal side of the arterial wall.

EP-A-461791, in the names of Julio C. Palmaz and the present inventors, relates to a prosthesis consisting of two attachment means, or stents, connected by means of a flexible coaxial tube, which is implanted along the arterial zone affected by the aneurysm.

With the current balloon devices, the attachment of stents on ends of a prosthesis is a tedious and time-consuming maneuver.

A device designed for attachment of stents also exists, described in US-A-3657744, which is not introducible by means of a catheter, and requires additional incisions in the zone to be repaired.

The technique of the introduction of catheters with inflatable balloons is known in valvuloplasty and angioplasty treatments, in which dilation catheters for one or more lumina are used.

If it is desired to implant with the current dilation catheters, the above mentioned prosthesis, consisting of two attachment means or stents, coaxially connected together by means of a flexible tube, it is necessary to use two catheters, one at a time, to consecutively dilate the proximal stent and the distal stent.

This maneuver is difficult and time-consuming, which is not recommendable.

US-A-4577631 describes a balloon device for implanting an intraluminal aortic prosthesis for repairing aneurysms, comprising a catheter having a longitudinal axis and at least three internal passages, first and second inflatable balloons disposed upon the catheter and separated by a predetermined distance, the second balloon having first and second ends and a longitudinal axis which is substantially parallel to the longitudinal axis of the catheter, the first end of the second balloon being disposed closer to the first balloon than the second end of the second balloon and the second end of the second balloon having an outlet for the catheter. The aortic prosthesis (e.g. a tubular graft including stents) coaxially overlies the catheter and balloons and is implanted by inflation of the balloons to bring the prosthesis into contact with the aortic wall.

When the device is used to implant a prosthesis close to the bifurcation of the iliac arteries (US-A-4577631; Fig. 9), the catheter turns down the iliac artery only after it has left the second balloon via the outlet along the axis of the second balloon.

The device of the invention, however, simplifies the maneuver and also solves the problem arising from implanting the prosthesis when the aneurysm is located in the abdominal aorta very close to the bifurcation of the iliac arteries.

According to the invention there is provided a balloon device for implanting an intraluminal aortic or aortobiiliac prosthesis for repairing aneurysms, comprising a catheter having a longitudinal axis and at least three internal passages, first and second inflatable balloons disposed upon the catheter and separated by a predetermined distance, the second balloon having first and second ends and a longitudinal axis which is substantially parallel to the longitudinal axis of the catheter, the first end of the second balloon being disposed closer to the first balloon than the second end of the second balloon and the second end of the second balloon having an outlet for the catheter, characterised by the features of the characterising portion of claim 1.

In a preferred mode of execution of the invention with said balloons, the first (distal) balloon is located close to the introduction end of said catheter, and second (proximal) balloon is located at a distance from the other which is proportional to the length of the prosthesis to be implanted.

Both the main object and the advantages of the device of the invention can be evaluated from the following description of the preferred mode of execution of the invention, with reference to the drawings.

FIG. 1 is a drawing showing the prosthesis at the moment of its implantation, and

FIG. 2 is a drawing of the form of the proximal balloon of the device of the invention.

While the invention will be described in connection with the preferred embodiment, it will be understood that it is not intended to limit the invention to that embodiment. On the contrary, it is intended to cover all alternatives, modifications, and equivalents as may be included within the scope of the invention as defined by the appended claims.

FIG. 1 shows a design of a portion of the abdominal aorta artery to be treated connected in its upper part with thoracic aorta 1, from which renal arteries 2 depart.

The abdominal aorta presents aneurysm 5, which goes from almost thoracic aorta 1 until bifurcation 10 of iliac arteries 11.

The treatment consists in implanting a prosthesis within the aneurysm 5, consisting of distal stent 4 sutured at one end to flexible liner 7 made of an inert material, such as dacron®, and sutured at the other end to another proximal stent 8.

As stated above, the stents 4, 8 are tubes of very

fine walls which, when pressure is exerted from the interior of same, dilate to form a tube of walls of greater diameter than the original tube diameter.

The increase in diameter of the stents 4, 8 is attained by means of balloons 3 and 9, which are introduced into the artery by means of catheter 6, which has lines or "lumina" in its interior, through which the fluid insufflated into the balloons 3, 9 passes.

An introducer and guide wire are used for placement of the unit, consisting of a metal wire which is made to pass through an incision in the femoral artery, monitoring the location of same by radioscopy.

After placing the introducer in the area of the aneurysm 5 to be treated, the catheter 6 is introduced, passing one of the lines by the introducer, the stents 4, 8 being previously mounted upon the balloons 3, 9 and compressed to the maximum to make their diameter smaller.

The tube, or liner 7, of inert material is between the two stents 4, 8 which are upon the balloons 3, 9.

When the distal stent 4 with its corresponding balloon 3 in its interior reaches the healthy wall located above the aneurysm 5, the introducer is withdrawn, and the balloon 3 is inflated up to its maximum diameter, as a result of which stent 4 takes the form indicated in FIG. 1, being implanted against the wall of the artery.

The procedure is the same with stent 8 and proximal balloon 9.

The inflation of balloons 6 and 9 can be done either simultaneously or alternately.

After the stents 4, 8 have been put into place, the balloons 3, 9 are deflated, and the catheter is withdrawn with same.

When the lower part of the aneurysm 5 is located close to bifurcation 10 of iliac arteries 11, as shown in FIG. 1, the correct attachment of proximal stent 8 has hitherto been difficult because in prior systems the catheter is not coaxial with the abdominal aorta, so that the pressure exerted by the proximal balloon against the interior wall of the stent is unequal.

For this reason, proximal balloon 9 takes the special form indicated in more detail in FIG. 2.

Proximal balloon 9 has outlet 13 of catheter 6 located at distance "d" from the balloon 9 longitudinal axis, which is approximately half the radius of balloon 9, and catheter 6 leaves balloon 9 at angle alpha of approximately 30 degrees in relation to the longitudinal axis of balloon 9.

The interior part of balloon 9 takes approximately saddle form 12, because same is located at bifurcation 10 of the iliac arteries.

When the aneurysm 5 involves iliac arteries 11, liner 7 of bifurcated tube form should be used, in which case proximal balloon 9 should have a diameter corresponding to that of iliac artery 11, and it should be coaxial to catheter 6 as well as distal balloon 3.

In the preferred form of execution of the device, catheter 6 has a length of between 50 and 75 cm, with thickness of between 1.6 and 3.3 mm (5 and 10 of the French scale), and it is made of polyvinyl chloride, for example, its distal end having a truncated conical point with blunt edges.

The central passage or central lumen of the catheter 6 will be used for introduction of the guide cord and also for injection of contrast substance. The other two passages, or lumina, will be used for the inflation and deflation of each of the balloons 3, 9.

In its turn, the catheter 6 will have surface marks every 15 cm and radiopaque marks at the beginning and end of each balloon 3,9.

In the preferred form of execution, the balloons 3, 9 are made of polyvinyl chloride or polyethylene and are of cylindrical form with blunt edges, with a length of between 3 and 5 cm along the catheter 6 and a diameter of between 16 and 30 mm.

It is to be understood that the invention is not limited to the exact details of construction, operation, exact materials or embodiment shown and described, as obvious modifications and equivalents will be apparent to one skilled in the are. Accordingly, the invention is therefore to be limited only by the scope of the appended claims.

Claims

1. A balloon device for implanting an intraluminal aortic or aortobiiliac prosthesis for repairing aneurysms, comprising a catheter (6) having a longitudinal axis and at least three internal passages, first and second inflatable balloons (3,9) disposed upon the catheter and separated by a predetermined distance, the second balloon (9) having first and second ends and a longitudinal axis which is substantially parallel to the longitudinal axis of the catheter (6), the first end of the second balloon (9) being disposed closer to the first balloon (3) than the second end of the second balloon and the second end of the second balloon (9) having an outlet (13) for the catheter, characterised in that each balloon (3,9) is connected to at least one of the internal passages, the catheter leaves the second end of the second balloon via the outlet (13) displaced from the longitudinal axis of the second balloon and at an angle of approximately thirty degrees with respect to the longitudinal axis of the second balloon.

2. The balloon device of claim 1, wherein the second balloon has a substantially tubular cross-sectional configuration with a radial dimension R, and the outlet (13) for the catheter is displaced from the longitudinal axis of the second balloon (9) at an approximate distance of 0.5R.

3. The balloon device of claim 1 or claim 2, wherein the second balloon (9) is coaxial with the catheter

(6).

4. The balloon device of any one of the preceding claims, wherein the catheter (6) has an introduction end and the first balloon (3) is located proximate the introduction end of the catheter and the second balloon is located at a distance from the first balloon which is proportional to the length of the prosthesis to be implanted.

5. The balloon device of any one of the preceding claims, wherein the first and second balloons each have a substantially tubular cross-sectional configuration with a radial dimension R about their longitudinal axes; the radial dimension R of the first balloon being greater than the radial dimension R of the second balloon.

Patentansprüche

1. Ballongerät zum Einpflanzen einer intraluminalen Aorten- oder Becken-/Beinarterien-Prothese zur Behebung von Aneurysmen, bestehend aus einem Katheter (6) mit einer Längsachse und zumindest drei inneren Kanälen, erste und zweite aufblasbare Ballons (3, 9), die auf dem Katheter angeordnet und durch eine vorgegebene Distanz voneinander getrennt sind, wobei der zweite Ballon (9) ein erstes und ein zweites Ende sowie eine Längsachse aufweist, die im wesentlichen parallel zur Längsachse des Katheters (6) verläuft, wobei das erste Ende des zweiten Ballons (9) näher am ersten Ballon (3) angeordnet ist als das zweite Ende des zweiten Ballons, und wobei das zweite Ende des zweiten Ballons (9) einen Auslaß (13) für den Katheter aufweist,
dadurch gekennzeichnet
daß jeder Ballon (3, 9) mit zumindest einem inneren Kanal verbunden ist, daß der Katheter das zweite Ende des zweiten Ballons über den Auslaß (13) verläßt, der von der Längsachse des zweiten Ballons versetzt ist, wobei der Winkel der Versetzung gegenüber der Längsachse des zweiten Ballons etwa dreißig Grad beträgt.

2. Ballongerät nach Anspruch 1,
dadurch gekennzeichnet,
daß der zweite Ballon eine im Querschnitt im wesentlichen röhrenförmige Konfiguration mit einem radialen Durchmesser R aufweist, und daß der Auslaß (13) für den Katheter von der Längsachse des zweiten Ballons (9) um einen ungefähren Abstand von 0,5 R versetzt ist.

3. Ballongerät nach Anspruch 1 oder Anspruch 2.
dadurch gekennzeichnet,
daß der zweite Ballon (9) koaxial zum Katheter (6) ist.

4. Ballongerät nach einem der vorhergehenden Ansprüche,
dadurch gekennzeichnet,
daß der Katheter (6) eine Einführungsspitze aufweist, daß der erste Ballon (3) unmittelbar neben der Einführungsspitze des Katheters angeordnet ist und daß der zweite Ballon mit einem Abstand zum ersten Ballon angeordnet ist, der der Länge der einzupflanzenden Gefäßprothese proportional ist.

5. Ballongerät nach einem der vorhergehenden Ansprüche,
dadurch gekennzeichnet,
daß der erste und der zweite Ballon jeweils eine im Querschnitt im wesentlichen röhrenförmige Konfiguration mit einem radialen Durchmesser R um ihre Längsachse aufweisen, wobei der radiale Durchmesser R des ersten Ballons größer ist als der radiale Durchmesser des zweiten Ballons.

Revendications

1. Dispositif à ballonnets pour implanter une prothèse intraluminale aortique ou pour les deux artères iliaques pour traiter les anévrismes, comprenant un cathéter (6) présentant un axe longitudinal et au moins trois passages internes, des premier et deuxième ballonnets gonflables (3,9) placés sur le cathéter et séparés par une distance prédéterminée, le deuxième ballonnet (9) présentant des première et deuxième extrémités et un axe longitudinal qui est sensiblement parallèle à l'axe longitudinal du cathéter (6), la première extrémité du deuxième ballonnet (9) étant placée plus près du premier ballonnet (3) que la deuxième extrémité du deuxième ballonnet, et la deuxième extrémité du deuxième ballonnet (9) présentant une sortie (13) pour le cathéter, caractérisé en ce que chaque ballonnet (3,9) est relié à au moins un des passages internes, le cathéter quitte la deuxième extrémité du deuxième ballonnet via la sortie (13) déplacée par rapport à l'axe longitudinal du deuxième ballonnet et selon un angle d'environ trente degrés par rapport à l'axe longitudinal du deuxième ballonnet.

2. Dispositif à ballonnets selon la revendication 1, selon lequel le deuxième ballonnet présente une configuration en coupe transversale sensiblement tubulaire avec une dimension radiale R, et la sortie (13) pour le cathéter est déplacée par rapport à l'axe longitudinal du deuxième ballonnet (9) selon une distance approximative de 0,5R.

3. Dispositif à ballonnets selon la revendication 1 ou la revendication 2, selon lequel le deuxième ballonnet (9) est coaxial au cathéter (6).

4. Dispositif à ballonnets selon l'une quelconque des

revendications précédentes, selon lequel le cathéter (6) présente une extrémité d'introduction et le premier ballonnet (3) est placé de manière proximale à l'extrémité d'introduction du cathéter et le deuxième ballonnet est placé à une certaine distance du premier ballonnet qui est proportionnelle à la longueur de la prothèse à implanter.

5. Dispositif à ballonnets selon l'une quelconque des revendications précédentes, selon lequel les premier et deuxième ballonnets présentent chacun une configuration en coupe transversale sensiblement tubulaire avec une dimension radiale R autour de leurs axes longitudinaux; la dimension radiale R du premier ballonnet étant supérieure à la dimension radiale R du deuxième ballonnet.

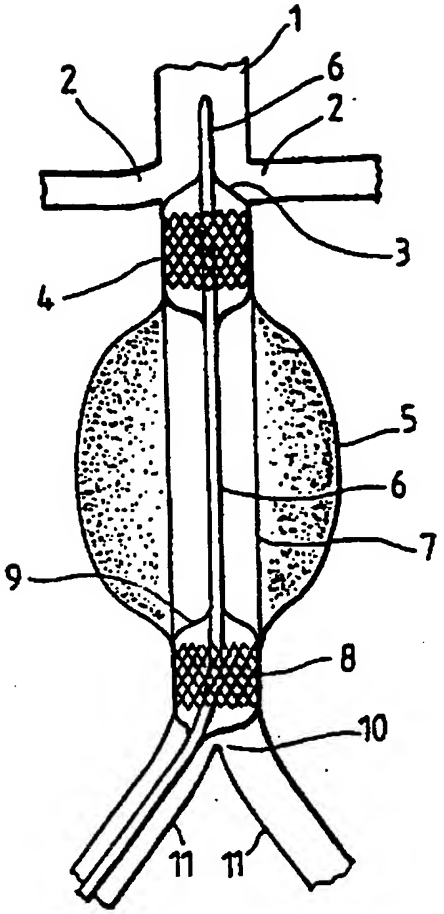

FIG.1

FIG.2